APR 17 2014

K131189

BECKMAN COULTER

Summary of Safety & Effectiveness
UniCel DxC SYNCHRON Systems Glucose (GLUH) reagent

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

1.0 **Submitted By:**

Yvette Lloyd
Consultant
Beckman Coulter, Inc.
250 S. Kraemer Blvd
Mail Stop: E1.SE.01
Brea, CA 92821
Phone: (714) 307-3469
FAX: (714) 961-4234
email: yrlloyd@beckman.com

2.0 **Date Submitted:**

April 4, 2014

3.0 **Device Name(s):**

3.1 **Proprietary Names**
UniCel DxC SYNCHRON Systems Glucose reagent (GLUH)

3.2 **Classification Name**
Glucose test system (21 CFR 862.1345, Product Code CFR)

4.0 **Predicate Devices:**

CANDIDATE	PREDICATE (K#)	Classification – Regulation	Classification Panel	Product Code
UniCel DxC SYNCHRON Systems GLUH	Beckman Coulter GLU assay (K883181)	Class II 862.1345	75 (Clinical Chemistry)	CFR

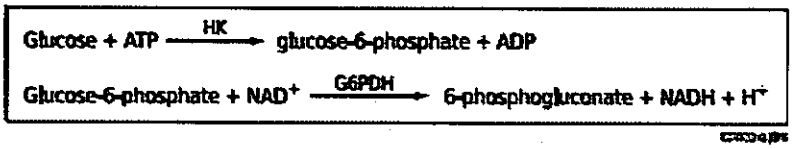
5.0 **Description:**

Reagent:

GLUH reagent is used to measure the glucose concentration by a timed endpoint method. In the reaction, hexokinase (HK) catalyses the transfer of a phosphate group from adenosine triphosphate (ATP) to glucose to form adenosine diphosphate (ADP) and glucose-6-phosphate. The glucose-6-phosphate is then oxidized to 6-phosphogluconate with the concomitant reduction of β-nicotinamide adenine dinucleotide (NAD) to reduced β-nicotinamide adenine dinucleotide (NADH) by the catalytic action of glucose-6-phosphate dehydrogenase (G6PDH).

The UniCel® DxC 600/800 SYNCHRON System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 100 parts reagent. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of glucose in the sample and is used by the System to calculate and express glucose concentration.

The GLUH uses the following chemical reaction scheme:



6.0 **Intended Use:**

INTENDED USE
UniCel DxC SYNCHRON Systems Glucose reagent (GLUH), when used in conjunction with UniCel® DxC 600/800 SYNCHRON System(s) and SYNCHRON Systems AQUA CAL 1 and 3, is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

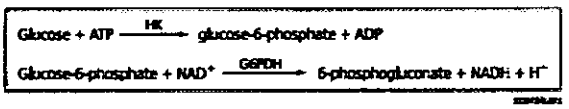
Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

7.0 **Comparison to Predicate(s):**

The following tables show the similarities and differences between the modified device and the predicate device identified in Section 4.0 of this summary.

List of design inputs that are same/similar between the two reagent devices

Characteristics	UniCel DxC SYNCHRON Systems GLUH Reagent	SYNCHRON Systems LX and UniCel DxC GLU reagent (K883181)
Intended Use	Same	Intended for the quantitative determination of glucose using serum, plasma, urine, or CSF as a sample type.

Clinical indications	Same	Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
Methodology	Same	Timed endpoint method
Reaction principle	Same	
Fundamental Technology	Same	Spectrophotometric detection
System use	Same (NOTE: GLUH is only applied to the DxC 600/800 systems)	For use on clinical chemistry analyzers
Analytic Range	Same	5-700 mg/dL
Reagent	Same	SYNCHRON Systems Glucose reagent, REAGENT CONSTITUENTS: Adenosine Triphosphate, 3.8 mmol/L; NAD+, 2.7 mmol/L; Hexokinase, 2.0 KIU/L; Glucose-6-phosphate dehydrogenase, 3.0 KIU/L; Also non-reactive chemicals necessary for optimal system performance.
Reference Intervals	Same	Sample type range Serum/plasma 74-106 mg/dL Urine 1-15 mg/dL Urine (timed) <0.5g/24 hours CSF 40-70 mg/dL
Sample Storage and Stability	Same	Serum/plasma 1. 8 hours at +20°C to +25°C 2. 48 hours at +2°C to +8°C 3. > 48 hours at ≤ -15 to -20°C Serum/plasma 1. 1 freeze/thaw cycle (when stored at -15 to -20°C)
Linearity	Same	Analytical range = 5-700mg/dL, with sample dilution using saline for samples exceeding the high end of the linear range.
Sample type	Same	Serum/plasma, CSF, urine
Within run Precision Claims	Same	SD – 2.0 mg/dL CV – 2.0%
Total Precision Claims	Same	SD – 3.0 mg/dL CV – 3.0%
Reagent On Board Stability	Same	30 days
Calibration stability	Same	14 days
Within lot calibration	Same	90 days

List of design inputs that are different between the two reagent devices

	UniCel DxC SYCNHRON Systems GLUH Reagent	SYNCHRON Systems LX and UniCel DxC GLU reagent (K883181)
Calibrator used	SYNCHRON Systems AQUA CAL 1 SYNCHRON Systems AQUA CAL 3 (K071277)	SYNCHRON MultiCal (K110251)
Calibrator Stability (opened)	30 days	20 days
Interferences		
Bilirubin	24 mg/dL	24 mg/dL
Hemoglobin	500 mg/dL	400 mg/dL
Lipemia	Low pool: Serum index = >6 (3+) (Human lipemia) Mid/High Pool: Serum index = 10(4+) (Human Lipemia)	400 mg/dL (4+) (Intralipid)
Ascorbic Acid	6.0 mg/dL	3.0 mg/dL
Urea	500 mg/dL	500 mg/dL
Uric Acid	40 mg/dL	20 mg/dL
EDTA	16 mg/dL	8 mg/dL
Creatinine	40 mg/dL	30 mg/dL
Anticoagulant	Lithium Heparin, Sodium Heparin, Potassium Oxalate/Sodium Fluoride	Ammonium Heparin, Lithium Heparin, Sodium Heparin, Potassium Oxalate/Sodium Fluoride
Sensitivity	≤5 mg/dL	<5mg/dL

8.0 **Summary of Non-clinical Performance Data:**

A series of studies were performed to evaluate the following non-clinical performance characteristics for the GLUH Reagent: method comparison, anticoagulant, precision, sensitivity, linearity, interferences, sample stability, sample dilution, reagent stability, reference range, and calibration stability experiments.

Method Comparison

Methods comparison experiments were designed using CLSI Procedure EP9-A2: "Method Comparison and Bias Estimation Using Patients Samples". The patient correlation studies were conducted using the SYNCHRON Glucose (GLU) (Method X) and the candidate UniCel DxC SYNCHRON Systems Glucose (GLUH) (Method Y) for serum and CSF matrices. Patient correlation studies were conducted using the SYNCHRON modular Glucose (GLUCm) (Method X) and the candidate Beckman Coulter UniCel DxC SYNCHRON Systems Glucose (GLUH) (Method Y) for urine samples. A minimum of 100 samples were tested for each matrix.

Platform	Sample	Slope	Intercept	R	N
UniCel DxC 600	Serum	0.982	-1.02	1.000	120
UniCel DxC 800	Serum	0.999	-1.60	1.000	120
UniCel DxC 600	CSF	0.978	1.25	1.000	100
UniCel DxC 800	CSF	1.002	-0.61	1.000	100

UniCel DxC 600	Urine	0.989	2.08	1.000	117
UniCel DxC 800	Urine	0.973	2.86	1.000	117

Anticoagulant Studies

Anticoagulant experiments were designed using CLSI Procedure EP14-A2: "Evaluation of Matrix Effects; Approved Guidelines – Second Edition". For each anticoagulant tested, paired plasma and serum samples from healthy volunteers were drawn. Over 50 patient specimens with glucose concentrations spanning the analytical range were obtained and tested internally.

DxC600		
Anticoagulant	**N**	**Deming Regression Analysis**
Sodium Heparin	79	y= 0.983 + 0.849, R= 0.999
Lithium Heparin	79	y= 0.994 + 0.393, R= 0.999
Sodium Fluoride/ Potassium Oxalate	79	y= 0.995 + 1.007, R= 0.999
DxC800		
Anticoagulant	**N**	**Deming Regression Analysis**
Sodium Heparin	58	y= 0.998 - 0.172, R= 0.999
Lithium Heparin	58	y= 1.02 - 2.476, R= 1.000
Sodium Fluoride/ Potassium Oxalate	58	y= 1.012 - 0.302, R= 0.999

Precision

Precision studies were conducted in accordance with CLSI EP5-A2. Multiple levels of samples were tested 4 times a day for 20 days. The user of a UniCel DxC 600/800 SYNCHRON System(s) should expect the instrument to produce imprecision values less than or equal to the claimed maximum performance limits (S.D. or % CV). The claimed within run SD is 2.0 mg/dL, and the claimed total SD is 3.0 mg/dL. The claimed within run %CV is 2.0, and the claimed total %CV is 3.0. The changeover value is 100.0 mg/dL.

Type of Imprecision	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points	GLUH GRAND MEAN (mg/dL)	SD	%CV
Within Run DxC 600	Serum	Control 1	1	80	43	0.7	1.6
	Serum	Control 2	1	80	219	2.3	1.0
	Serum	Control 3	1	80	390	5.7	1.5
	Serum	Pool 1	1	80	9	0.3	3.6
	Serum	Pool 2	1	80	101	1.1	1.1
	Serum	Pool3	1	80	660	6.4	1.0
	Urine	Pool 1	1	80	10	0.3	3.2
	Urine	Pool 2	1	80	95	0.9	1.0
	Urine	Pool 3	1	80	670	5.2	0.8
	CSF	Pool 1	1	80	11	0.3	3.0

	CSF	Pool 2	1	80	109	1.3	1.2
	CSF	Pool3	1	80	677	7.0	1.0
Total DxC 600	Serum	Control 1	1	80	43	0.8	1.9
	Serum	Control 2	1	80	219	2.6	1.2
	Serum	Control 3	1	80	390	6.5	1.7
	Serum	Pool 1	1	80	9	0.6	5.9
	Serum	Pool 2	1	80	101	1.6	1.6
	Serum	Pool3	1	80	660	8.4	1.3
	Urine	Pool 1	1	80	10	0.6	5.7
	Urine	Pool 2	1	80	95	1.4	1.5
	Urine	Pool 3	1	80	670	6.1	0.9
	CSF	Pool 1	1	80	11	0.6	5.3
	CSF	Pool 2	1	80	109	1.6	1.5
	CSF	Pool3	1	80	677	8.6	1.3

Type of Imprecision	SAMPLE TYPE	SAMPLE	No. Systems	No. Data Points	GLUH GRAND MEAN (mg/dL)	SD	%CV
Within Run DxC 800	Serum	Control 1	1	80	43	0.5	1.2
	Serum	Control 2	1	80	219	2.7	1.2
	Serum	Control 3	1	80	389	6.3	1.6
	Serum	Pool 1	1	80	9	0.3	3.2
	Serum	Pool 2	1	80	101	1.1	1.1
	Serum	Pool3	1	80	662	7.5	1.1
	Urine	Pool 1	1	80	10	0.3	3.0
	Urine	Pool 2	1	80	94	1.2	1.2
	Urine	Pool 3	1	80	668	7.9	1.2
	CSF	Pool 1	1	80	11	0.3	2.3
	CSF	Pool 2	1	80	108	1.1	1.0
	CSF	Pool3	1	80	680	6.7	1.0
Total DxC 800	Serum	Control 1	1	80	43	0.7	1.7
	Serum	Control 2	1	80	219	3.5	1.6
	Serum	Control 3	1	80	389	7.2	1.9
	Serum	Pool 1	1	80	9	0.3	3.6
	Serum	Pool 2	1	80	101	1.2	1.2
	Serum	Pool3	1	80	662	9.4	1.4
	Urine	Pool 1	1	80	10	0.4	3.7
	Urine	Pool 2	1	80	94	1.3	1.3
	Urine	Pool 3	1	80	668	8.1	1.2
	CSF	Pool 1	1	80	11	0.4	3.6
	CSF	Pool 2	1	80	108	1.7	1.6
	CSF	Pool3	1	80	680	8.1	1.2

Analytical Sensitivity (Limits of detection)
Limit of blank (LoB), limit of detection (LoD), and Limit of Quantitation (LoQ) data analyses were performed in accordance with the CLSI EP17-A2 guideline. Multiple urine, CSF and serum pools were run over multiple days to establish and verify the analytical sensitivity claims. The claimed LoB, LoD and LoQ values are ≤5mg/dL.

	Serum	CSF	Urine
LoB	0.19 mg/dL	0.17 mg/dl	0.19 mg/dL
	0.011 mmol/L	0.009 mmol/L	0.011 mmol/L
LoD	1.74 mg/dL	1.68 mg/dL	1.78 mg/dL
	0.097 mmol/L	0.093 mmol/L	0.099 mmol/L
LoQ	3.78 mg/dL	3.67 mg/dL	3.69 mg/dL
	0.210 mmol/L	0.204 mmol/L	0.205 mmol/L

Linearity
The study followed CLSI EP-6A. The testing involves running multiple replicates of the pools over the range of the assay. The concentration Recovery error and %Recovery error were calculated for each sample tested. The recovered concentrations verses the Target concentrations are curve fit with first, second, and third order polynomials. The residual differences for each level between the first order (linear) and the better fitting higher order (second or third polynomial) known as the Nonlinearity Differences are calculated. The data substantiates GLUH test is linear between 5 and 700 mg/dL.

The following are the final linear equations obtained for each matrix:

DxC 600
Serum: y= 1.01016x + 1.0881
CSF: y = 1.0075x + 1.5157
Urine: y= 1.0011x + 0.4464

DxC 800
Serum: y=1.0035x + 2.1977
CSF: y = 1.0081x + 1.5778
Urine: y= 0.9991x -+ 1.068

Interferences
Interference studies were designed from CLSI Guideline EP7-A: "Interference Testing in Clinical Chemistry – Approved Guideline" and used to assess common or known substances which could interfere with the UniCel DxC SYNCHRON Systems GLUH assay. The experiment involves adding potential interfering substances to patient serum pools to determine the magnitude of the effect. A properly operating UniCel DxC 600/800 SYNCHRON System(s) should exhibit interference values less than or equal to: ± 6 mg/dL or 10%, with a crossover value of 60 mg/dL.

Low Level Glucose Pool					
Substance	Source	Maximum Level Tested	Target (mg/dL)	Recovered (mg/dL)	% recovery*
Hemoglobin	RBC hemolysate	500 mg/dL	45.3	43.7	96.5
Bilirubin	Bovine	24 mg/dL	43.4	42.5	97.9
Lipemia	Human	(3+)	46.4	45	97

		Serum Index = 6			
Ascorbic Acid	NA	6.0 mg/dL	43.7	43.8	100.2
Urea	NA	500 mg/dL	54.7	55.2	100.9
Uric Acid	NA	40 mg/dL	42.9	44.4	103.5
EDTA	NA	16 mg/dL	43.6	43.4	99.5
Creatinine	NA	40 mg/dL	45.2	44.4	98.2
Mid Level Glucose Pool					
Substance	Source	Maximum Level Tested	Target (mg/dL)	Recovered (mg/dL)	% recovery*
Hemoglobin	RBC hemolysate	500 mg/dL	171.5	169.1	98.6
Bilirubin	Bovine	24 mg/dL	168.7	167.9	99.5
Lipemia	Human	(4+) Serum Index = >10	189.1	184.6	97.6
Ascorbic Acid	NA	6.0 mg/dL	167.7	166.4	99.2
Urea	NA	500 mg/dL	207.1	208.9	100.9
Uric Acid	NA	40 mg/dL	166.8	168.4	101
EDTA	NA	16 mg/dL	167	168.1	100.7
Creatinine	NA	40 mg/dL	173.8	173.4	99.8
High Level Glucose Pool					
Substance	Source	Maximum Level Tested	Target (mg/dL)	Recovered (mg/dL)	% recovery*
Hemoglobin	RBC hemolysate	500 mg/dL	410.7	406.1	98.9
Bilirubin	Bovine	24 mg/dL	407.2	404.8	99.4
Lipemia	Human	(4+) Serum Index = >10	461.7	453.1	98.1
Ascorbic Acid	NA	6.0 mg/dL	396.2	394.6	99.6
Urea	NA	500 mg/dL	476	477.4	100.3
Uric Acid	NA	40 mg/dL	397.1	405	102
EDTA	NA	16 mg/dL	402.6	404.4	100.4
Creatinine	NA	40 mg/dL	409.4	411.5	100.5

Listings of drugs, diseases and other pre-analytical variables known to affect glucose measurements when analyzing Serum, Urine and CSF are described in References (1,2,3). Visually turbid urine specimens should be centrifuged prior to analysis.

References:

1. Young, D. S., Effects of Drugs on Clinical Laboratory Tests, 5th Edition, AACC Press, Washington, D. C. (2000).

2. Friedman, R. B., Young, D. S.,Effects of Disease on Clinical Laboratory Tests, 4th Edition, AACC Press, Washington, D.C. (2001).

3. Young, D. S., Effects of Preanalytical Variables on Clinical Laboratory Tests, 3rd Edition, AACC Press, Washington, D. C. (2007).

Sample dilution

The objective of this testing is to determine and verify the appropriate sample diluent to use when diluting out of range samples using the UniCel DxC SYNCHRON Systems Glucose (GLUH) reagent. Saline was chosen as the appropriate diluent. There was no issue or effect observed when verifying saline as an appropriate sample diluent.

Reagent stability

The UniCel DxC SYNCHRON Systems Glucose (GLUH) Reagent was tested to verify the on-board stability claim on the UniCel DxC 600/800 SYNCHRON System(s) family of Clinical Chemistry analyzers. The performance assessment involves assaying multiple levels of pooled sera at regular intervals throughout the testing period. The assay was calibrated at 14 day intervals. To be considered acceptable, recovered values must fall within the expected ranges. The testing establishes that the GLUH reagent is stable on board for 30 days.

Reference range

Samples reference intervals are based on published literature references.

Sample	Literature reference
Serum/Plasma	74-106 mg/dL
Urine	1-15 mg/dL
Urine (timed)	<0.5g/24 hours
CSF	40-70 mg/dL

Literature References

Tietz, N. W., ed., Fundamentals of Clinical Chemistry, 6th Edition, W. B. Saunders, Philadelphia, PA (2007).

Pagana, K D and Pagana, T J, Mosby's Manual of Diagnostic and Laboratory Tests 3rd Edition , Mosby Inc., St Louis, MO (2006).

9.0 Conclusion:

The data for the UniCel DxC SYNCHRON Systems Glucose Reagent (GLUH), in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the currently cleared SYNCHRON Systems Glucose Reagent (GLU, K883181). Equivalence is demonstrated through method comparison, anticoagulant, precision, sensitivity, linearity, interferences, sample stability, sample dilution, reagent stability, reference range, and calibration stability experiments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

BECKMAN COULTER, INC.
YVETTE LLOYD
250 S. KRAEMER ST
BREA CA 92821

Re: K131189
Trade/Device Name: UniCel DxC SYNCHRON Systems Glucose Reagent (GLUH)
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR
Dated: April 11, 2014
Received: April 14, 2014

Dear Ms. Lloyd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131189

Device Name
UniCel DxC SYNCHRON Systems Glucose Reagent (GLUH)

Indications for Use *(Describe)*
UniCel DxC SYNCHRON Systems Glucose Reagent (GLUH), when used in conjunction with UniCel DxC 600/800 SYNCHRON System(s) and SYNCHRON Systems AQUA CAL 1 and 3, is intended for the quantitative determination of glucose concentration in human serum, plasma, urine or cerebrospinal fluid (CSF).

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."